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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,466	01/28/2002	Chung-Ming Chen	01-1278-D	4947

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,466

Applicant(s)

CHEN ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendment has been acknowledged. Claims 2-32 have been canceled. Claim 1 is pending and considered before the examiner.

Specification

1. The disclosure is objected to because of the following informalities:
2. The specification has recited Table I-III in the content. However, the Table I-III found at the bottom of the specification lack the paper numbers at the top of the pages and it is confusing for the Office whether these Tables are the Tables referred in the content of the specification. If the Tables belong to the part of the specification, please incorporate the Tables into the body of the specification by adding the page number for each Table.
3. An appropriate correction is required.

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:
5. This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a division of Application No. 09/597,951, filed 06/20/2000, now patent SN. 6,355,449, which claims priority of application of 08/690,196, filed on July 29, 1996, now abandoned." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using two nutrient indicators produce two identical detectable signals for detecting two bacterial enzymes after each of them is cleaved by its corresponding enzyme with or without further reacting with developing agent, does not reasonably provide enablement for

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making and using two nutrient indicator to detect more than two bacterial enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

8. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See *United States v. Theketronic Inc.*, 8USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *gain in re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

9. 1) & 2). State of Art and Unpredictability of the art.

10. The state of art teaches that the chromogenic or fluorogenic enzyme substrates have been used in microbial diagnoses. Each unique enzyme can cleave certain kind of substrates.

However, the art does not teach one substrate or nutrient indicator can be cleaved by more than one enzyme to produce two distinctive and distinguishable detectable signals. Therefore, it is unpredictable for using two nutrient indicators to detect more than two bacterial enzymes.

11. While there are many bacterial substrates as chromogen and fluorogen in the art and the wavelengths of each chromogen or fluorogen vary and some of them may not be known. The mixture of two chromogenic or fluorogenic may change the wavelength as they are originally emitted or influence each other for hardly to distinguish the specificity of the signal. Therefore it is a none-routine experimentation and highly unpredictable.

12. 3) & 4). Number of working examples and amount of guidance.

13. Applicants only teach a vancomycin resistance *Enterococci* contains nutrient indicators of α -nitrophenyl- β -D-glycopyranoside, which is the substrate or nutrient indicator of *enterococcus* β -glucosidase and produces a yellow color, and L-pyroglutamic acid β -naphthylamine, which is the nutrient indicator of pyrrolidonyl arylamidase and produces a pink of yellow color upon the addition of p-dimethylainocinnamaldehyde (See Examples 1&2 on page 32-35).

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14. However, specification presents no working examples of two nutrient indicators can be cleaved by more than two bacterial enzymes and produce more than two detectable and distinguishable signals for more two bacterial enzymes.

15. 5) Scope of the claims.

16. The claims broad read on a medium contains two nutrient indicators that is used for detect more than two or more bacterial enzymes.

17. 6) & 7) Nature of the invention and Lever of the skill in the art.

18. The invention is a bacterial detection system by simultaneously detection of more than two enzymes with combination of two bacterial specific nutrient indicators. It requires a knowledge and rich experience of handling the bacterial culture and bacterial biochemical metabolic chromogen and fluorogenic reactions at the level of Ph. D of microbiology.

19. Given the above analysis of the factors, which the courts have determined are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-13 of U.S. Patent No. 6,355,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scopes of the conflict claims are overlapping.

22. Patent "449" is directed to a bacterial growth medium for detecting vancomycin Enterococci in a sample that contains two nutrient indicators besides Vancomycin, wherein the first indicator is a substrate for the first bacterial enzyme, which provides a first detectable signal after it is cleaved by the first bacterial enzyme of β -glucosidase, and the second nutrient indicator, which is the substrate for the second bacterial enzyme, which provides second signal after it is cleaved by the second bacterial enzyme, such as pyrrolidonyl arylamidase as an intermediate molecule (See claims 1-13),

23. The current applicant is directed to a medium for detecting two or more bacterial enzymes comprising first nutrient indicator, which is a substrate for the first bacterial enzyme, which provides a first detectable signal after it is cleaved by the first bacterial enzyme, and the second nutrient indicator, which is the substrate for the second bacterial enzyme, which provides second signal after it is cleaved by the second bacterial enzyme upon reacting with a developing agent. Moreover, according to the disclosure of the specification, the two specific enzymes are directed to β -glucosidase and pyrrolidonyl arylamidase (See lines 6-13 on specification 6).

24. Because the Patent "499" claims a species of a medium comprising two particular nutrient indicators, whereas the current Application claims a generic medium comprising any or all two nutrient indicators, the current application is obvious type double patenting over the claims 1-13 of the US. Patent No. 6,355,499B1

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Panosian et al. (J. Clin. Micro. 1989, Vol. 27, No. 8, pp. 1719-1722).

26. Panosian et al. disclose a medium comprising two enzyme substrates in the medium, wherein the said enzyme substrates are para-nitrophenyl- α -D-galactopyranoside (PGAL) and 4-methylumbiliferyl- β -glucopyranoside (MGLU), which is used for a rapid detecting streptococcus

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bovis by measuring the presence of two bacterial enzymes: α -galactosidase and β -glucosidase. The said two enzyme substrates, para-nitrophenyl- α -D-galactopyranoside (PGAL) and 4-methylumbiliferyl- β -glucopyranoside (MGLU) can be specially hydrolyzed by α -galactosidase and β -glucosidase and produce two distinct detectable signals respectively in the presence of another chemical agent sodium dexychole (See abstract, lines 29-38 on the 1st col. Lines 1-20 on the 2nd col. Of page 1719 and lines 11-38 on the 1st col. Of page 1720).

27. According to the disclosure of the specification, both α -galactosidase and β -glucosidase are listed as the target bacterial enzyme embodiment for the current application (See lines 16-17 on page 12 of specification), and both para-nitrophenyl- α -D-galactopyranoside (PGAL) and 4-methylumbiliferyl- β -glucopyranoside (MGLU) are listed as the nutrient indicators embodiment that are intended in current application (See lines 14-23 on page 15 of specification). While both para-nitrophenyl- α -D-galactopyranoside (PGAL) and 4-methylumbiliferyl- β -glucopyranoside (MGLU) are not named as nutrient indicators by Panosian, they are structurally and functionally identical compounds to the disclosure of specification as nutrient indicators, they are considered as nutrient indicators. Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

August 18, 2003

